

House File 541 - Introduced

HOUSE FILE _____
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HSB 25)

Passed House, Date _____ Passed Senate, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

1 An Act relating to the regulation and practice of pharmacy,
2 including providing for the establishment of a limited drug
3 and device distributor license.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
5 TLSB 1092HV 82
6 jr/es/88

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1 1 Section 1. Section 155A.3, subsection 5, Code 2007, is
1 2 amended to read as follows:
1 3 5. "College of pharmacy" means a school, university, or
1 4 college of pharmacy that satisfies the accreditation standards
1 5 of the ~~American accreditation council on pharmaceutical for~~
1 6 ~~pharmacy education as to the extent those standards are~~
1 7 adopted by the board, or that has degree requirements which
1 8 meet the standards of accreditation adopted by the board.
1 9 Sec. 2. Section 155A.3, Code 2007, is amended by adding
1 10 the following new subsections:
1 11 NEW SUBSECTION. 22A. "Limited drug and device
1 12 distributor" means a person operating or maintaining, either
1 13 within or outside this state, a location at which limited
1 14 noncontrolled prescription drugs, prescription devices, and
1 15 medical gases, are distributed to patients in this state
1 16 pursuant to a prescription drug order; or a person operating
1 17 or maintaining a location at which limited quantities of
1 18 drugs, devices, or medical gases are distributed at wholesale
1 19 in this state. A "limited drug and device distributor" does
1 20 not include a pharmacy licensed pursuant to this chapter or a
1 21 drug wholesaler providing prescription drugs to patients in
1 22 this state pursuant to a drug manufacturer's prescription drug
1 23 assistance program.
1 24 NEW SUBSECTION. 23A. "Medical gas" means a gas or liquid
1 25 oxygen intended for human consumption.
1 26 Sec. 3. Section 155A.4, subsection 2, Code 2007, is
1 27 amended by adding the following new paragraph:
1 28 NEW PARAGRAPH. h. A limited drug and device distributor,
1 29 licensed by the board, to distribute limited noncontrolled
1 30 prescription drugs, prescription devices, and medical gases,
1 31 to patients in this state pursuant to rules adopted by the
1 32 board.
1 33 Sec. 4. Section 155A.9, subsection 1, Code 2007, is
1 34 amended to read as follows:
1 35 1. A college of pharmacy shall not be approved by the
2 1 board unless the college is accredited by the ~~American~~
2 2 ~~accreditation council on pharmaceutical for pharmacy~~
2 3 education.
2 4 Sec. 5. Section 155A.29, subsection 1, Code 2007, is
2 5 amended to read as follows:
2 6 1. Except as specified in subsection 2, a prescription for
2 7 any prescription drug or device which is not a controlled
2 8 substance shall not be filled or refilled more than eighteen
2 9 months after the date on which the prescription was issued and
2 10 a prescription which is authorized to be refilled shall not be
2 11 refilled more than ~~eleven~~ twelve times.
2 12 Sec. 6. NEW SECTION. 155A.42 LIMITED DRUG AND DEVICE
2 13 DISTRIBUTOR LICENSE.
2 14 1. A person shall not act as a limited drug and device
2 15 distributor without a license. The license shall be
2 16 identified as a limited drug and device distributor license.
2 17 2. The board shall establish, by rule, standards for

2 18 limited drug and device distributors and may define specific
2 19 types of limited drug and device distributors. The board
2 20 shall identify, by rule, specific prescription drugs or
2 21 classes of noncontrolled prescription drugs, including
2 22 quantities of such drugs, which may be distributed by a
2 23 limited drug and device distributor.

2 24 3. The board shall adopt rules pursuant to chapter 17A
2 25 relating to the issuance of a limited drug and device
2 26 distributor license. The rules shall provide for conditions
2 27 of licensure, compliance standards, licensure fees,
2 28 disciplinary action, and other relevant matters.

2 29 4. The board may deny, suspend, or revoke a limited drug
2 30 and device distributor's license for failure to meet the
2 31 applicable standards or for a violation of the laws of this
2 32 state, another state, or the United States relating to
2 33 prescription drugs or controlled substances, or for a
2 34 violation of this chapter, chapter 124, 124A, 124B, 126, 205,
2 35 or 272C, or a rule of the board.

3 1 EXPLANATION

3 2 This bill defines a limited drug and device distributor and
3 3 provides for the establishment of a limited drug and device
3 4 distributor license, including the establishment of compliance
3 5 standards and requirements unique to the operations of those
3 6 businesses. The board is required to identify, by rule,
3 7 certain noncontrolled prescription drugs, including quantities
3 8 of such drugs, that may be distributed by a limited drug and
3 9 device distributor.

3 10 Limited drug and device distributors would include home
3 11 medical device suppliers, medical oxygen distributors, and
3 12 other currently nonlicensed entities engaged in the
3 13 distribution to consumers of limited noncontrolled
3 14 prescription drugs, medical devices, and medical gases
3 15 pursuant to a prescriber's authorization. A limited drug and
3 16 device distributor would also include a location that
3 17 distributes limited quantities of drugs, devices, or medical
3 18 gases at wholesale.

3 19 The bill corrects references to the American council on
3 20 pharmaceutical education pursuant to the council's recent name
3 21 change to the accreditation council for pharmacy education.

3 22 The bill also increases to 12 refills the number of times a
3 23 prescription for a noncontrolled prescription drug may be
3 24 refilled within an 18-month period.

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